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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,527	03/30/2004	Alpern Robert	ILPS 04021.101	6886
58415 SENNIGER PO	7590 06/05/2007 OWERS (ILPS)	EXAMINER		
ONE METRO	POLITAN SQUARE		LEVY, NEIL S	
16TH FLOOR ST. LOUIS, MO 63102			ART UNIT	PAPER NUMBER
22.200,			1615	
			NOTIFICATION DATE	DELIVERY MODE
			06/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

	Application No.	Applicant(s)				
·	10/814,527	ROBERT ET AL.				
Office Action Summary	Examiner	Art Unit				
• • • • • • • • • • • • • • • • • • •	NEIL LEVY	1615				
The MAILING DATE of this communication app						
Period for Reply		·				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (8) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
,	Responsive to communication(s) filed on <u>25 April 2007</u> .					
·—	,—					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) <u>1,3,5-20,22 -27,35-59</u> is/are pending in the application.						
4a) Of the above claim(s) 3,11,17 -20,22-27 & 45-59 is/are withdrawn from consideration.						
	5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1,12-16 and 35-44</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1,3,5-20,22 -27,35-59 are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examine	<b>r.</b>					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
The oath of declaration is objected to by the Ex	aminer. Note the attached Office	Action of form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary (PTO-413) Paper No(s)/Mail Date					
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5)  Notice of Informal F 6)  Other:					

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#### **DETAILED ACTION**

### Election/Restrictions

Applicant's election without traverse of Group I, species of acid resin in the reply filed on 4/2/07 is acknowledged.

Claim3, 5-11, 17-20, 22-27, 45-59 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species , there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/2/07.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 12-16, 36-38, 40-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering an acid resin rats with compromised kidney function

, does not reasonably provide enablement for ANY acid resin to any animal with any disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to Practice the invention commensurate in scope with these claims. The human model studies are written as prophetic, intended studies; no results are evident. Applicant presumes beneficial results will be achieved in hypertension, cirrhosis, edema, pre-eclampsia, pregnancy, acidosis, heart failure and other conditions of fluid overload, permitting reduction of dialysis, calcium channel blockers, and other drugs. The specification presents no basis for the practitioner to know that any administered acid resin in any amount will in fact result in amelioration of any of the claimed conditions. Extensive experimentation, inclusive of the use of models would be needed to identify if any of the claimed results could be obtained.

The said resin is described as loaded with NH4, H or K. There is no other description of this species, as far as examiner can determine.

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# Claim Rejections - 35 USC § 102

# Claim Rejections - 35 USC § 103

Claim1,12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DADEY-5935599.

The instant resins (column 3, summary; column 9, bottom) are administered to patients with nephropathology (column 1, lines 50-53) thus would result in the instant claimed effects-Na binding.

## Double Patenting

Claim1, 12, 35-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1, 5, 8-17, 30 of copending Application No10/965274. Although the conflicting claims are not identical, they are not patentably distinct from each other because 965 would anticipate the instant claim, as the same acid resins are administered.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 57/1-272-1-009.

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Primary Examiner Art Unit 1615